

# Nanobiotix: 2016 review and 2017 anticipated milestones

Paris, France and Cambridge, Massachusetts, USA, January 31, 2017 – NANOBIOTIX (Euronext: NANO – ISIN: FR0011341205), a late clinical-stage nanomedicine company pioneering novel approaches for the local treatment of cancer, today provides its activities and achievements during 2016 and an overview of anticipated 2017 milestones.

#### 1. 2016 Review

#### 2016: NBTXR3 clinical development

• The Soft Tissue Sarcoma (STS) PII/III trial has progressed well (one trial through Europe and Asia)
This indication is the most advanced in Nanobiotix's pipeline. The "Act.In.Sarc" pivotal trial (<a href="www.actinsarc.com">www.actinsarc.com</a>), is currently ongoing in 13 countries through Europe and Asia (via PharmaEngine).

In November, Nanobiotix announced that the target of 104 patients (2/3 of patients) needed for the interim readout was reached, with 115 patients randomized and 153 having signed the inform consent out of the total of 156 STS evaluable patients expected in this trial.

• Head and Neck cancer positive interim results in European PI/II trial and launch of a new PI/II trial in Asia
The Company reported preliminary positive results from phase I/II trial (treated with radiotherapy alone plus NBTXR3) in July. Safety and feasibility have been achieved at the first 3 dose levels and data has shown preliminary positive signs of antitumoral effect in all evaluable patients.

PharmaEngine, Nanobiotix's partner for the Asia-Pacific area, has launched a new clinical trial in October in head and neck cancer patients treated with radiotherapy and NBTXR3 plus chemotherapy. This is the seventh clinical trial with NBTXR3.

#### Prostate cancer trial launch in the U.S.

Nanobiotix announced that the US Food and Drug Administration (FDA) has approved the first Company's Investigational New Drug (IND) application, allowing the Company to launch its first Phase I/II prostate cancer trial in the US.

The recruitment of patients has started at Ronald Reagan UCLA Medical Center, Los Angeles CA. Two other centers are involved: Thomas Jefferson University Hospital PA, Philadelphia and Dana Farber Cancer Institute, Boston MA.

• <u>Liver cancers (HCC & met) PI/II trial in Europe, positive preliminary results</u> In December Nanobiotix released positive results from phase I/II trial. Preliminary data shown feasibility and good safety of treatment with NBTXR3 in liver cancers at 10% dose level.

## 2016: NBTXR3 first filing for market authorization in Europe

According to plan, the Company filed for certification of NBTXR3 in August 2016 based on the level of clinical and scientific evidence available at that time. LNE/G-MED, the French notified body, has given guidance that the review of results for a potential CE mark could be expected in 2017.

## 2016: Opening a new application in immuno-oncology for lead product NBTXR3

## Expansion into immuno-oncology, preclinical results: Proof of Concept (POC)

After 11 months of development, the Company presented preclinical data at the annual meeting of the Society for Immunotherapy of Cancer (SITC), demonstrating that NBTXR3 actively stimulates the host immune system to attack

tumor cells. Study results suggest NBTXR3's potential to transform the tumor into an in-situ vaccine.

On top of the Company's core development activities, these findings could open new collaborations for NBTXR3 through combinations with other immuno-oncology drugs.

#### 2016: Corporate & financial events

#### • U.S. reinforcement of the management

Nanobiotix strengthened its U.S. leadership team with the appointments of Dr. Mihail Obrocea as the Head of U.S. Clinical Development and Noël Kurdi as the Director of Investor Relations. These additions contribute to the strengthening of the Company's clinical development and leverage U.S. investors' potential, to continue the growth of the Company.

#### • € 21.3M private placement

Completion of a private placement of EUR 21.3 million. The investor base consisted primarily of life sciences specialists, the majority of which were from the United States.

### • <u>US \$1M milestone payment from Taiwan-based partner PharmaEngine</u>

The USD 1m payment from PharmaEngine has been triggered by the injection of the first patient undergoing treatment in Nanobiotix' Soft Tissue Sarcoma (STS) pivotal phase in Asia.

#### • € 2M Grant from Bpifrance

In September, Bpifrance has awarded the Company an interest-free loan of €2M for Innovation (Prêt à Taux Zéro pour l'Innovation - PTZI).

## 2. 2017 Forthcoming news flow: pivotal milestones

This year the Company could receive its first market approval with NBTXR3 (CE Mark), which would open access to the product for cancer patients.

In parallel, the ongoing clinical trials with NBTXR3 in seven indications will deliver several read-outs this year.

The Company is also expanding its exciting developments in Immuno – Oncology (IO), broadening the potential value of NBTXR3 with new applications for the product.

2017 should be full of remarkable events, enhancing Nanobiotix medical and scientific value and bringing Nanobiotix to the next level.

#### **NBTXR3** to market

#### • Interim readout STS PII/III trial and commercialization plan

Nanobiotix is expecting the analysis by an independent committee of interim STS Phase II/III results, to determine whether if the continuation of the trial is possible. Nanobiotix plans to release the conclusion of this analysis around spring 2017.

The independent committee of experts, will (i) review the data related to the primary endpoint (Complete Pathological Response Rate), (ii) ensure the safety of all patients enrolled in the study, (iii) evaluate the quality of the data collected, and (iv) assess the continued scientific validity of the study design. This analysis will be performed on two third of the treated patients (104 patients).

Assuming positive outcomes from the interim Phase II/III data readout, the Company will thereafter communicate its overall plan for the European commercialization of NBTXR3.

## • 1st European market authorization expected in 2017

Nanobiotix anticipate that it may receive its first market authorization in 2017. This approval would allow Nanobiotix to start diffusing its product in European market. Following the CE marking and availability of the complete data of the Phase II/III (act.in.sarc study), the Company will commence negotiations in different countries to seek product reimbursement.

#### **NBTXR3** clinical expansion

Nanobiotix continues its clinical expansion and expects to release data this year, increasing NBTXR3's value.

• Head and Neck cancer, PI/II data presentation and plan for next steps

In the second half of 2017 the Company aims to present complete data from the Phase I/II trial.

This indication holds great potential, and the Company will issue this year the clinical development plan of this indication, that could potentially take place in EU and in the U.S.

#### Prostate cancer, preliminary PI/II data

The first trial launched in the U.S. in 2016 should deliver this year (H2 2017) preliminary PI/II data on safety and feasibility.

• <u>Liver metastasis and primary liver cancer: completion of Phase I recruitment, population selection for Phase II</u>

By the end of 2017, Nanobiotix should complete patients' recruitment of the phase I part, and may proceed to the selection of patient population for the dose-expansion part of the trial.

#### Immuno Oncology (IO) developments

In parallel to its core developments, Nanobiotix will continue developing its Immuno-Oncology program and present new results in 2017.

This program could lead at medium term to new potential collaborations with pharma companies developing immunooncology drugs.

The abovementioned information are detailed in the press releases previously issued by the Company and available on its website: <a href="http://www.nanobiotix.com/">http://www.nanobiotix.com/</a> en/news/

#### 3. 2017 Financial calendar

Nanobiotix will announce its financial and operating results according to the following indicative calendar:

- February 28, 2017 Revenue for Q4 2016
- April 28, 2017 2016 Annual results
- May 15, 2017 Revenue for Q1
- June 14, 2017 Annual General Meeting Paris, France
- July 12, 2017 Revenue for Q2
- August 31, 2017 Half year results
- November 15, 2017 Revenue for Q3

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## About NANOBIOTIX: www.nanobiotix.com

Nanobiotix (Euronext: NANO / ISIN: FR0011341205) is a late clinical-stage nanomedicine company pioneering novel approaches for the local treatment of cancer. The Company's first-in-class, proprietary technology, NanoXray, enhances radiotherapy energy with a view to provide a new, more efficient treatment for cancer patients.

NanoXray products are compatible with current radiotherapy treatments and are meant to treat potentially a wide variety of solid tumors including soft tissue sarcoma, head and neck cancers, liver cancers, prostate cancer, breast cancer, glioblastoma, etc., via multiple routes of administration.

NBTXR3 is being evaluated in: soft tissue sarcoma (STS), head and neck cancers, prostate cancer, and liver cancers (primary and metastases). Additionally, head and neck cancer and rectal cancer trials led by Nanobiotix's Taiwanese partner, PharmaEngine, are underway in the Asia Pacific region. The Company has filed in August 2016 for market approval (CE Marking) in Europe for its lead product NBTXR3.

Nanobiotix is listed on the regulated market of Euronext in Paris (ISIN: FR0011341205, Euronext ticker: NANO, Bloomberg: NANO: FP). The Company Headquarter is based in Paris, France. Affiliate in Cambridge, United States.

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This press release and the information that it contains do not constitute an offer to sell or subscribe for, or a solicitation of an offer to purchase or subscribe for, Nanobiotix shares in any country.

NBTXR3 is currently under development in clinical studies with the purpose of obtaining a CE mark in the future. At the moment NBTXR3 does not bear a CE mark and is not permitted to be placed on the market or put into service until NBTXR3 has obtained a CE mark.